CIBA Vision®
A Novartis Company

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7 May 2004

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No 2004D-0042
Consumer Directed Broadcast Advertising of Restricted Devices

To Whom it May Concern:

CIBA Vision Corporation, a U.S. based manufacturer of ophthalmic medical devices, is submitting these comments in reference to the draft FDA guidance document entitled "Consumer Directed Broadcast Advertising of Restricted Devices" (Guidance), the availability of which was published in the February 10, 2004 Federal Register. Our comments include 1) change recommendations specific to the proposed guidance and 2) a device specific request to consider removing restricted device status from some of our contact lens products.

Based on our understanding of the device and drug regulations, along with our practical experience with historical regulation of contact lenses, we propose for your consideration the following changes to the draft guidance:

(a) Recognize that reminder advertisements which merely identify the trade name and established name of the device and do not contain any representation concerning the safety or effectiveness of the device, including indications or directions of use, are exempt from a "brief statement" requirement, and

(b) clarify that compliance with the "brief statement" requirement [see §502(r) of the Federal Food, Drug, and Cosmetic Act (Act)] for broadcast media advertisements can be ordinarily satisfied by:

(i) including one or more approved/cleared indications,

(ii) identifying the most serious and common warnings, precautions, side effects, and contraindications (collectively referred to as "risks") which are **relevant** to both the indication(s) being advertised and to the risks justifying "restricted device" status for the advertised indication(s), and

(iii) providing some type of adequate provision mechanism for the dissemination of full prescribing information.

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Related to the discussion of restricted devices, and recognizing that not all prescription devices are considered restricted devices, we request that the Agency rescind the restricted device status for Class III, PMA approved 7-day extended wear lenses with or without a UV additive,[1] as discussed below:

- That restricted device status for these lenses is not necessary and is inconsistent with the statutory standard. The Act limits "restricted device" status to those devices for which, because "of their potentiality for harmful effects or collateral measures necessary for their use," there cannot be reasonable assurance of their safe and effective use without special restrictions upon their sale, distribution, or use (see §§520(e) and 515(d) (1) (B) (ii) of the Act). We note that print and broadcast media advertisements for 7-day extended wear lenses with or without UV have not historically been required to contain a brief statement of the relevant risks[2] and there simply does not exist any new data or information which would justify imposing a brief statement requirement for such advertisements. Indeed, 7-day extended wear with or without UV have for years been regulated as prescription devices without any independent requirement for a brief statement. The available information, and clinical and regulatory experience, establishes that restricted device status is not necessary to provide reasonable assurance of the safety and effectiveness of 7-day extended wear.

Please see the discussions below for additional details and commentary on these two issues.

1) Additional Discussion - Comments to Draft Restricted Device DTC Guidance

(a) Reminder Advertisements

It is respectfully submitted that advertisements for prescription devices which merely identify the trade name and established name of the device and do not contain any representations concerning the safety and effectiveness of the device, including indications and directions of use, should be exempt from any "brief statement" requirement. The exempt status of reminder advertisements for prescription drugs (see 21 C.F.R. § 202.1(e) (2) (ii)) would seem to be equally applicable to reminder advertisements for restricted devices. Under such circumstances, a requirement for a brief statement would appear to be unnecessary and, as is the case with prescription drugs, so-called reminder advertisements should be specifically exempted from the brief statement requirement.

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[1] It is also our opinion that, under the statutory standard (Section 520(e) of the Act), 30-day extended wear lenses should not be subject to restricted device status. However, in view of the relatively short marketing history in the US of these lenses, we are not, at this time, requesting that their restricted device status be rescinded.

[2] With the exception of 30-night lenses, prior to 2003 the conditions of approval for contact lenses subject to PMAs did not seek to impose a "brief statement" requirement. The approval letters for 7-day extended wear lenses did not purport to impose prescription limitations in accordance with Section 502(e) of the Act. Similarly, while approval letters for UV lenses required that all advertising and promotional materials for such lenses contain the prescribed UV warning and note, the letters specifically noted that FDA was not requiring a "brief statement." It was not until early 2003 that FDA changed the conditions of approval for 7-day extended wear lenses and UV lenses subject to PMA and PMA Supplement approval orders so as to impose a "brief statement" requirement. Significantly, this change was adopted without any prior notice, discussion, or factual or legal justification being provided.

(b) Brief Statement

It is respectfully submitted that broadcast media advertisements for restricted devices should be considered to be in compliance with §§502(q) and (r) of the Act if:

- The advertisements are neither false nor misleading within the meaning of §§201(n) and 502(q) of the Act;
- The advertisement identifies one or more of the approved/cleared indications;
- The advertisement contains a "brief statement" of the risk information that is ***relevant*** to the advertised indication(s) and the risks justifying restricted device status for the advertised indication(s); and
- that it is recommended the Ad include at least one type of adequate provision mechanism to allow for the dissemination of full prescribing information.

Since it is our understanding that the recently published draft guidance on "Consumer-Directed Broadcast Advertising of Restricted Devices" requires that a broadcast advertisement identify ***all*** **of the devices' intended uses and *all* of the most important precautionary information,** it should be clarified or modified. Specifically, the Guidance should be changed to allow the sponsor of the advertisement to select one or more uses (but not necessarily **all**) upon which to base the advertisement, and, concomitantly, to limit the content of the risk statement to that relevant to the uses being advertised. In this respect, the above-referenced Guidance should adopt a regulatory framework analogous to that provided by regulation of the advertisement of prescription drugs. Specifically, under 21 C.F.R. §§ 202.1(e) (3) (ii) and (a):

> "(ii) The information relating to effectiveness is not required to include information relating to all purposes for which the drug is intended but may optionally be limited to a true statement of the effectiveness of the drug for the selected purpose(s) for which the drug is recommended or suggested in the advertisement ...
>
> > (a) The side effects and contraindications disclosed may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement..."

Medical devices subject to restricted device status should not ordinarily be required to provide information relating to risks not relevant to the uses being advertised or unrelated to the restricted device status of the advertised product. Thus, for example, advertisements for UV-absorbing contact lenses should not ordinarily be required to include a brief statement if the ad makes no claims pertaining to UV protection.[3] If the advertisement does claim UV protection, the brief statement should be required to extend only to those warnings, precautions, side effects, and contraindications directly relating to the UV attributes of the lens. Similarly, if advertisements for contacts approved for 30-day wear do not contain any representations for 30-day wear (i.e., the ad only indicates daily wear use[4]), the advertisement should not be required to include a brief statement, and if the ad makes claims concerning 30-day wear, then the brief

[3] As explained previously, it is our opinion that restricted device status for Class III, PMA approved 7-day extended wear lenses (with or without UV) should be rescinded.

[4] Daily wear contacts (with or without UV) are subject to Class II, Premarket Notification 510(k) requirements and are therefore not considered restricted devices (daily wear contacts are subject to FTC, not FDA, oversight).

statement should be required to extend only to those warnings, precautions, side effects, and contraindications directly relating to 30-day wear.

In other words, broadcast media advertisements for UV containing or 30-day wear contact lenses should not be required to include, as part of the "brief statement," warnings, precautions, side effects, and contraindications which are not relevant to the representations contained in the advertisements or to the risks justifying restricted device status. Of course, if, in light of the representations made in these advertisements, warnings, precautions, side effects, and contraindications not related to the lenses' restricted device status nevertheless become material, the body of the advertisement would, under the Act and the Federal Trade Commission Act, be required, as part of fair balance, to include a conspicuous reference to the relevant precautionary information.

Regarding the FDA's draft proposal for adequate provision requirements, we request that the wording be modified to state that it is a recommendation to include in the Ad at least one adequate provision mechanism of the four approaches provided. Our request is based on the following considerations:

- Unlike drug requirements, there is no statutory requirement in the FD&C Act (or medical device amendments) or device regulation establishing a legal requirement for adequate provision.
- It would be unreasonable, if not unduly burdensome, for some smaller device manufacturer's to establish all of the adequate provision approaches normally required of drug DTC broadcast Ads.

2) Additional Discussion - Restricted Device Status of 7-Day Extended Wear Lenses With or Without UV Additive[5]

Although the federal register notice has called for comments specific to the draft restricted device DTC guidance, for the ophthalmic device industry there is the related issue of designation of restricted device status, especially for some of our Class III, PMA approved extended wear contact lenses.

It is respectfully submitted that "restricted device" status is inappropriate where the safety and effectiveness of a medical device, such as 7-day extended wear lenses with or without UV, can be reasonably assured without imposing special restrictions on its sale, distribution, or use. In the case of contact lenses, the applicable general Class II and Class III regulatory controls, including requirements for PMA or 510(k) clearance, adherence to QSR regulations, prescription limitations, and the prohibition against false or misleading promotional materials (including failure to reveal material facts in light of representations made (see §201(n) of the Act)) are adequate to provide reasonable assurance of safety and effectiveness and therefore "restricted device" status for such products is not necessary.

In the case of marketed contact lenses, the potential for harmful effects and the need for collateral measures simply do not rise to the magnitude where special restrictions on marketing, distribution, or use are justified. While it is true that in the absence of

[5] See footnote 3.

"restricted device" status, advertisements for all contact lenses would be subject to FTC, rather than FDA jurisdiction, FTC's authority over such advertisements is adequate to assure that such advertisements are not false or misleading in any particular. Indeed, advertisements for non-UV daily wear and 7-day extended wear contact lenses have for years been adequately regulated by the FTC.

Summary & Conclusions

CIBA Vision therefore respectfully requests that the Guidance document be revised to: (a) exclude from its scope reminder advertisements; (b) clarify that information relating to "intended uses" do not have to identify all of the approved/cleared intended uses; (c) clarify that information relating to "relevant warnings, precautions, side-effects, and contraindications" is ordinarily satisfied when the advertisement provides the most significant risk information relevant to the advertised intended uses and the product's restricted device status and (d) clarify that is it is a recommendation that some type of adequate provision mechanism be included in the Ad to identify how or where the complete prescribing information may be obtained .

In addition, we request that CDRH rescind the restricted device status for Class III, PMA approved 7-day extended wear lenses with our without UV additive as being unnecessary and inconsistent with the statutory requirements for restricted device status.

Respectfully, and on behalf of CIBA Vision Corporation,

Paul G. Oris, RAC Head, Global Regulatory Affairs	Alicia M. Plesnarski, RAC Director, Global Regulatory Affairs